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Indian Standard
SPECIFICATION FOR RESIN-BASED DENTAL FILLING MATERIALS

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SPECIFICATION FOR RESIN-BASED DENTAL FILLING MATERIALS

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Indian Standard
SPECIFICATION FOR RESIN-BASED DENTAL FILLING MATERIALS

0. FOREWORD

0.1 This Indian Standard was adopted by the Indian Standards Institution on 30 November 1981, after the draft finalized by the Dental Materials Sectional Committee had been approved by the Chemical Division Council.

0.2 Resin-based dental filling materials are used for restoration of teeth. However, precise definition of a composite filling material is yet to be agreed upon. The title and scope of this standard are, therefore, such as not to exclude any resin-based material, but include resin-based composite type of filling materials.

0.3 This standard is based on ISO 4049-1978 Resin-based dental filling materials, prepared by the International Organization for Standardization (ISO).

0.4 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with the IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard prescribes the requirements and the methods of sampling and test for resin-based dental filling materials presented in a form suitable for both mechanical and hand mixing, and intended for use as direct dental restorations in the oral cavity.

2. REQUIREMENTS

2.1 Material — When treated in accordance with the manufacturer's instructions, the material shall set to a condition suitable for its intended dental use (*see also* **2.4**).

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*Rules for rounding off numerical values (*revised*).

2.2 Colouring Matter — If the material is supplied in pre-coloured shades, then each shade shall be capable of satisfying the requirements specified in the standard. In the event of the material being supplied for tinting or blending to the user's prescription, the test requirements shall apply both when the maximum recommended proportion of tinter or blender is used and with the base material by itself (*see also* **2.8**).

2.3 Working Time — The working time from the commencement of mixing to the commencement of setting, when determined as prescribed in **A-2**, shall be not less than the mixing time plus 60 s.

2.4 Setting Time — The setting time measured from the commencement of mixing, when determined as prescribed in **A-3**, shall be not more than 8 min.

2.5 Transverse Strength — The transverse strength of the set material, when determined as prescribed in **A-4**, shall be not less than 50 MPa.

2.6 Shade — The colour of the set material shall closely match the manufacturer's shade guide. If a shade guide is not supplied by the manufacturer, samples from two further batches shall be taken for comparison purposes.

2.7 Toxicity — The mixed material, when used in accordance with the manufacturer's instructions, shall neither cause prolonged damage to oral tissues nor have any adverse systemic effect.

2.8 Colour Stability

2.8.1 *Heat* — The colour of the set material shall not show more than a slight change after 24 h, when tested as prescribed in **A-5.1**.

2.8.2 *Light* — The colour of the set material shall not show more than a slight change after 24 h, when tested as prescribed in **A-5.2**.

2.9 Fillers — Resin-based materials may or may not contain fillers. Those with 50 percent or more by mass of filler shall be described as composite. The filler content shall be determined by the method prescribed in **A-6**.

3. PACKING AND MARKING

3.1 Packing — The material shall be packed in securely closed containers that will not contaminate nor be affected under normal conditions of transport, storage and handling.

3.2 Marking — Each package shall be legibly and indelibly marked with the following information:

a) Name of the material, and composite, if applicable;

b) Shade;

c) Name of the manufacturer and or his recognized trade-mark, if any;

d) Net mass;

e) Date of manufacture and expiry date; and

f) Batch number.

3.3 Manufacturer's Instructions — Detailed instructions shall accompany each individual pack of material and shall include the following details:

a) Information of the proportioning of components and method of mixing, including, if relevant, ambient conditions under which it should be carried out;

b) Information on the manipulation (*see* Note) and setting time of the material, including an indication of the time when a matrix may be removed, if this differs from the setting time;

c) Any special precautions regarding manipulation of the material, including, if relevant, the maximum proportion of tinters or blenders which may be used without detriment to the physical properties;

d) Information on the need to use a base/liner or other recommended protective measures if the material can cause pulpal irritations;

e) Recommended instructions for finishing; and

f) Recommended conditions for storage (need for refrigeration) and shelf life under the conditions of storage.

NOTE — The term 'manipulation time' is intended to refer to the time the manufacturer claims is available for handling and placement of his particular product. This may well be different from the minimum 'working time'.

4. SAMPLING

4.1 The method of drawing representative samples of the material and the criteria for conformity of the material to the requirements of this specification shall be as prescribed in Appendix B.

APPENDIX A

(*Clauses* 2.3, 2.4, 2.5, 2.8.1,2.8.2 *and* 2.9)

METHODS OF TEST FOR RESIN-BASED DENTAL FILLING MATERIALS

A-1. GENERAL

A-1.1 Quality of Reagents — Unless specified otherwise, pure chemicals and distilled water (*see* IS : 1070-1977*) shall be employed in tests.

> NOTE — 'Pure chemicals' shall mean chemicals that do not contain inpurities which affect the results of analysis.

A-1.2 Ambient Conditions — Unless stated otherwise, all test specimens shall be prepared and tested at 27 ± 1°C. The relative humidity shall be controlled to ensure that it remains greater than 30 percent at all times.

A-1.3 Mixing — The material shall be mixed in accordance with the manufacturer's instructions, using only the amount necessary to carry out the relevant test.

A-2. WORKING TIME

A-2.1 Apparatus

A-2.1.1 *Oscillating Rheometer* — It records graphically or instrumentally the viscosity changes in the setting material. A suitable instrument which comprises the following features is shown in Fig. 1.

> The main housing (*A*) is mounted and can rotate in a ball-race (*B*), which has very little friction. The lower platten (*C*) is held in the main housing by two grub screws (*D*) and a knurled screw (*E*), with upper platten (*M*) in position on its guide, a distance of 1 mm above. The main housing and the lower platten are driven in an oscillatory motion by means of a 10 min^{-1} electric motor attached to an eccentric wheel (*F*) which is connected to arm (*G*) by means of two balanced and tensioned coil springs (*H*). The maximum rotary movement of arm (*G*), when no material is on the platten, is 1° 12′ ± 2′. This rotary movement is measured by means of a transducer (*N*), the output from which is fed either to a centre-zero microammeter or to a suitable automatic recording apparatus. The instrument is checked by attaching a fine nylon thread to a hook (*J*). A-10·2 g mass is attached to the other end of the thread, which passes over a polytetrafluoroethylene (PTFE) rod. Hence, a force of 0·1 N is applied at right angles to arm (*G*)

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*Specification for water for general laboratory use (*second revision*).

at point (*J*) which is 54 mm from the centre of platten (*C*). This is equivalent to a torque of 5·4 N. mm. When this calibration torque is applied, screws (*K*) and (*L*) are so adjusted that the deflection on the microammeter is the same as the deflection obtained when the instrument is running with no material on the platten.

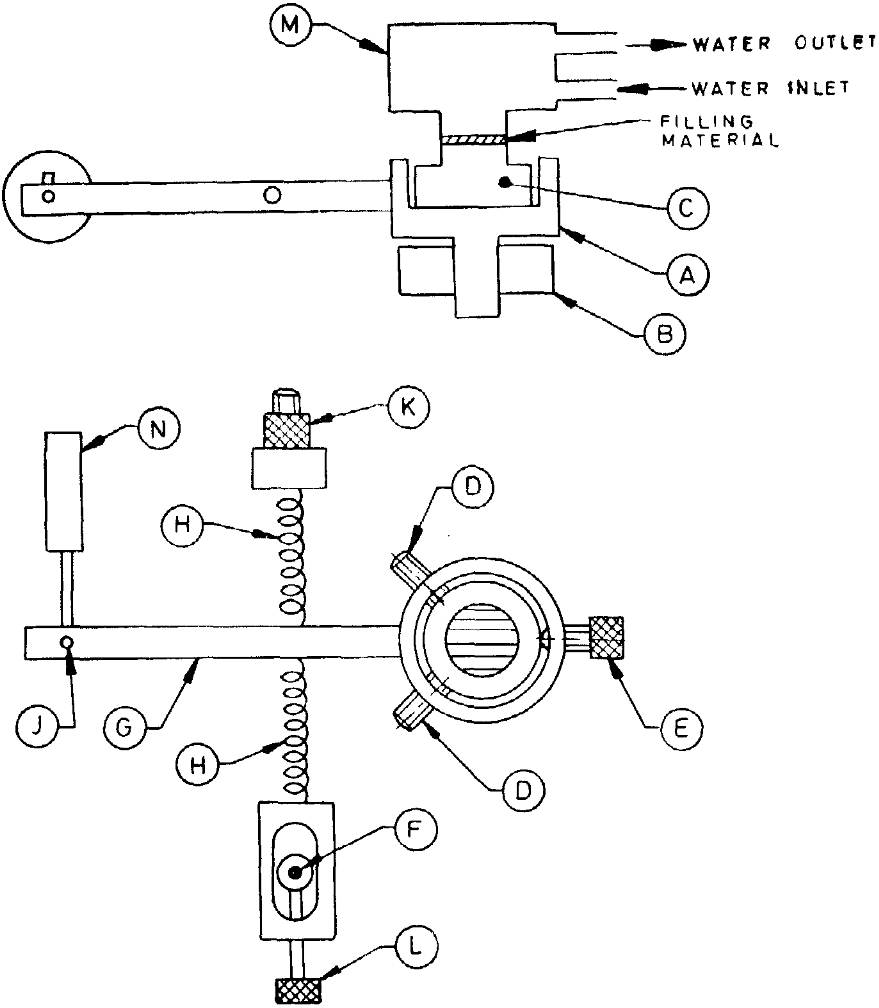
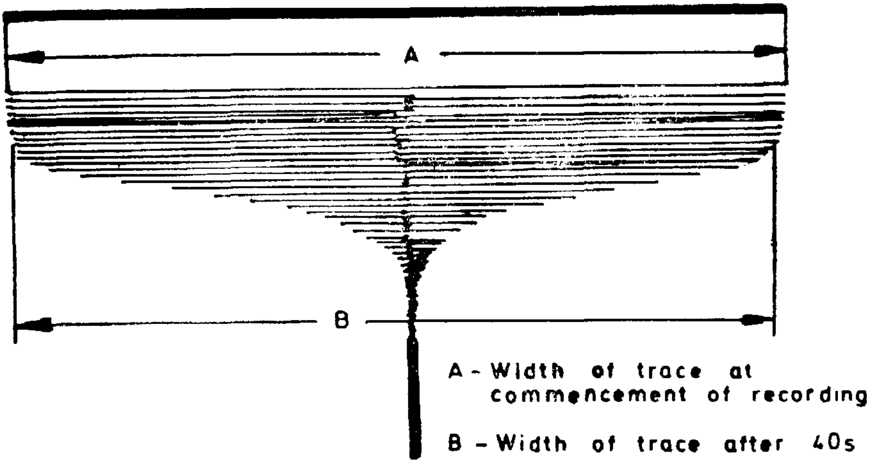
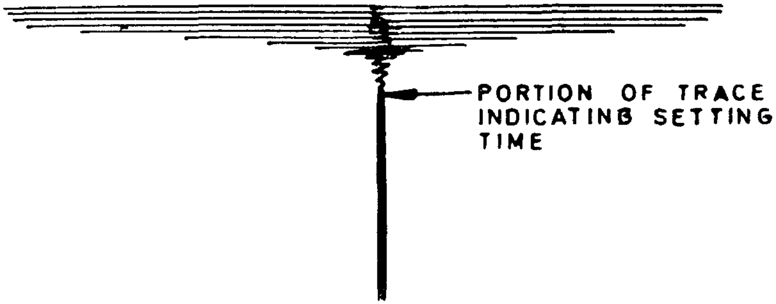


Fig. 1 Oscillating Rheometer for Determination of Working Time and Setting Time

A-2.2 Procedure — Mix the test material in accordance with the manufacturer's instructions. Start timing from the commencement of mixing. Place the mixed material on platten (*C*) and lower the upper platten (*M*) on its guide and screw into position 20s after the end of mixing. Maintain the water circulating through patten (*M*) at 27 ± 1°C. Take readings, one every 6s, on one side of the meter and plot these values against time. Alternatively, the transducer output may be fed into a suitable automatic recording apparatus and a continuous trace of variation of viscosity with time may be obtained (as shown in Fig. 2).


A
B
A - Width of trace at commencement of recording
B - Width of trace after 40s

2A TRACE FOR VERIFICATION OF MINIMUM WORKING TIME



2B TRACE FOR DETERMINATION OF SETTING TIME

FIG. 2 TRACES OF VISCOSITY AS A FUNCTION OF TIME

A-2.3 Calculation — Measure the trace 40s after commencing recording (1 min after the end of mixing), when it shall be not less than 95 percent of the original width.

A-3. SETTING TIME

A-3.1 Apparatus — Same as specified in **A-2.1**.

A-3.2 Procedure — Repeat the procedure specified in **A-2.2** using water at 37 ± 1°C circulating through platten (*M*).

A-3.3 Calculation — From the curve obtained (*see* Fig. 2), record the setting time as the time at which the curve flattens out to the final straight portion. Alternatively, the setting time may be recorded as the time at which the curve deviates from its final straight portion.

A-4. TRANSVERSE STRENGTH

A-4.1 Apparatus

A-4.1.1 *Metal Mould* — PTFE* lined, for preparation of a specimen $25 \pm 2 \times 2 \pm 0{\cdot}1 \times 2 \pm 0{\cdot}1$ mm. A suitable mould is illustrated in Fig. 3.

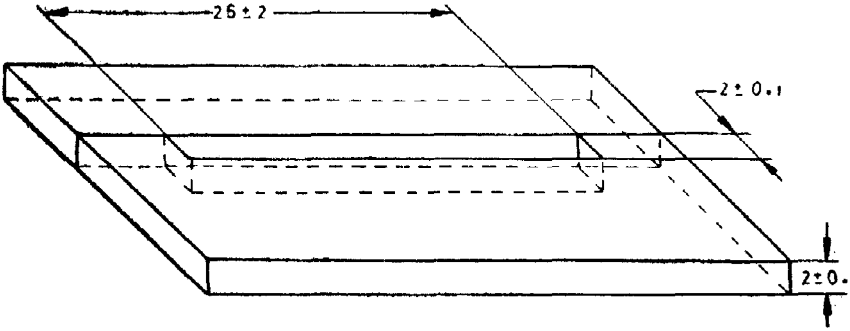


FIG. 3 MOULD FOR PREPARATION OF TEST SPECIMEN

A-4.1.2 *Two Plates* — of or lined with PTFE or other suitable material, approximately 25 × 25 mm.

A-4.1.3 *Small Clamp*

A-4.1.4 *Suitable Testing Apparatus* — with jig for application of loading in the manner specified in **A-4.3**. The jig consists essentially of two rods (2 mm diameter) mounted parallel with 20 mm between centres, and a third rod (2 mm diameter) between and parallel to the other two, so that the three rods in combination can be used to give a three-point loading to the specimen.

---

*PTFE tape of thickness 0·05 to 0·20 mm is suitable.

A-4.2 Preparation of Test Specimen — Mix the material according to the manufacturer's instructions and immediately place in the mould situated on a PTFE plate. Place the second PTFE plate on top of the mould and gently apply pressure by means of the clamp, thus exuding excess material from the mould. Three minutes after the commencement of mixing, place the assembly in a water bath maintained at 37°C. Fifteen minutes after the commencement of mixing, remove the clamp and separate the mould. Store the specimen in water at 37°C.

A-4.3 Procedure — Twenty-three hours after the commencement of mixing, transfer the specimens to a second bath of water, at 27 ± 1°C. Fifty minutes later, remove the specimen, wipe dry and place in the transverse testing jig in the testing apparatus. Twenty-four hours after the commencement of mixing, apply a load to the specimen at 0·75 ± 0·25 mm/min cross head speed, or at 50 ± 16 N/min if an incremental loading apparatus is used.

A-4.4 Calculation — The transverse strength A is given, in newtons per square millimetre (megapascals), by the formula :

$$A = \frac{3Fl}{2\,bd^2}$$

where

F = maximum force in newtons exerted on the specimen,

l = distance in mm between the supports (correct to 0·01 mm),

b = breadth in mm of the specimen measured immediately prior to testing (correct to 0·01 mm), and

d = depth in mm of the specimen measured immediately prior to testing (correct to 0·01mm).

Calculate the mean of three or more values from a total of five determinations, and report the result to three significant figures. Discard any value for individual specimens which fall more than 15 percent below the mean of the five, and report the mean of the remaining values. Repeat the whole test if more than two of the specimens have to be discarded.

A-5. COLOUR STABILITY

A-5.1 Heat

A-5.1.1 *Apparatus*

A-5.1.1.1 *Metal moulds* — PTFE lined*, suitable for preparing specimens of diameter 15 ± 1 mm and thickness 0·5 ± 0·10 mm.

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*PTFE tape of thickness 0·05 to 0·20 mm is suitable.

A-5.1.1.2 *Clamps* — suitable for use with the moulds.

A-5.1.1.3 *Oven* — capable of being controlled at 37 ± 1°C.

A-5.1.1.4 *Oven* — capable of being controlled at 60 ± 2°C.

A-5.1.2 *Procedure* — Prepare the resin paste according to the manufacturer's instructions and fill a pair of lined moulds. Clamp the moulds and transfer them, within 3 min of the commencement of mixing, to the oven, controlled at 37 ± 1°C. After 1 h, timed from the commencement of mixing, take the moulds from the oven and remove the two specimen discs. Place one disc in the oven, controlled at 60 ± 2°C, for a further 23 h and return the other disc to the oven, controlled at 37 ± 1°C, for the same period of time. Remove both discs from their respective ovens and compare them using unaided visual examination in diffuse daylight. Only a slight change in colour shall be permissible. Retain the disc from the 37°C oven for use as a control specimen in the procedure specified in **A-5.3**.

A-5.2 Light

A-5.2.1 *Apparatus*

A-5.2.1.1 *Metal moulds* — Same as in **A-5.1.1.1**.

A-5.2.1.2 *Clamps* — Same as in **A-5.1.1.2**.

A-5.2.1.3 *Oven* — Same as in **A-5.1.1.3**.

A-5.2.1.4 *Cabinet with adjustable ventilation* — Containing a xenon lamp radiation source, and a turn table capable of being rotated at 33 min^{-1}.

A-5.3 Procedure — Prepare the resin paste according to the manufacturer's instructions and fill a lined mould. Clamp the mould and transfer it, within 3 min of the commencement of mixing, to the oven controlled at 37 ± 1°C. After 1 h, timed from the commencement of mixing, remove the specimen disc and blank off half the surface to be exposed to light with metal foil. Place the specimen in a glass dish centred on the turntable and cover the specimen with water to a depth of 5 to 20 mm. Position the specimen so that it is 75 mm from the centre of the dish and its uppermost surface is 350 to 400 mm directly below the xenon lamp. Maintain the specimen at a temperature of 37 ± 1°C, by adjusting the cabinet ventilation, and expose it to the radiation for 23 h with the turntable rotating at 33 min^{-1}. Replace any water lost by evaporation, so that the specimen is always covered to a depth of between 5 and 20 mm. After 23 h exposure, remove the specimen from the water and dry with an absorbent cloth or tissue. Mark a comparison between the exposed and unexposed areas of the test specimen, and then between the exposed portion and the control specimen from the heat test (**A-5.1.2**). Only a slight change in colour shall be permissible using unaided visual examination in diffuse daylight.

A-6. FILLER CONTENT

A-6.1 Apparatus

A-6.1.1 *Muffle Furnace* — Capable of being controlled at 575±25°C.

A-6.1.2 *Crucible*

A-6.2 Preparation of Test Specimen — Mix sufficient material to provide a test specimen of mass approximately 0·5 g.

A-6.3 Procedure — Heat the crucible in the muffle furnace for 15 min at 575±25°C, allow to cool in a desiccator and weigh to the nearest 0·001 g. Place the test specimen in the crucible and weigh the whole to the nearest 0·001 g.

A-6.3.1 Heat the crucible and specimen in the furnace at 575±25°C for 30 min. Then carefully remove the crucible with its contents, allow to cool in a desiccator and weigh to the nearest 0·001 g. Repeat the cycle of heating, cooling and weighing until the mass is constant to within 0·001 g. Carry out the test on three specimens and report the mean.

A-6.4 Calculation

$$\text{Filler content, percent by mass} = \frac{M_3 - M_1}{M_2 - M_1} \times 100$$

where

M_1 = mass in g of the crucible,
M_2 = mass in g of the crucible and the material, and
M_3 = mass in g of the crucible and the material after heating.

APPENDIX B

(*Clause* 4.1)

SAMPLING OF RESIN-BASED DENTAL FILLING MATERIALS

B-1. GENERAL REQUIREMENTS

B-1.0 In drawing, preparing, storing and handling test samples, the precautions and directions given in **B-1.1** to **B-1.7** shall be observed.

B-1.1 Samples shall not be taken in an exposed place.

B-1.2 The sampling instrument shall be clean and dry.

B-1.3 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

B-1.4 To draw a representative sample, the contents of each container selected for sampling shall be mixed as thoroughly as possible by suitable means.

B-1.5 The samples shall be placed in clean, dry, air-tight glass or other suitable containers.

B-1.6 The sample containers shall be of such size that they are almost completely filled by the sample.

B-1.7 Each sample container shall be sealed air-tight with a suitable stopper after filling, and marked with full details of sampling, the date of sampling and the year of manufacture of the material.

B-2. SCALE OF SAMPLING

B-2.1 Lot — All the containers in a single consignment of the material drawn from a single batch of manufacture shall constitute a lot. If a consignment is declared or known to consist of different batches of manufacture the containers belonging to the same batch shall be grouped together and each such group shall constitute a separate lot.

B-2.1.1 Samples shall be tested from each lot for ascertaining conformity of the material to the requirements of the specification.

B-2.2 The number of containers to be chosen from the lot shall depend on the size of the lot and shall be as given in Table 1.

B-2.3 The containers shall be selected at random from the lot and in order to ensure the randomness of selection, the random sampling methods given in IS : 4905-1968* may be followed.

TABLE 1 NUMBER OF CONTAINERS TO BE SELECTED FOR SAMPLING

(*Clauses* B-2.2 *and* B-3.1.1)

LOT SIZE (1)	NUMBER OF CONTAINERS TO BE SELECTED (2)
Up to 50	3
51 to 200	4
201 to 400	5
401 to 650	6
651 to 1 000	7

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*Methods for random sampling.

B-3. TEST SAMPLES AND REFEREE SAMPLE

B-3.1 Preparation of Test Samples

B-3.1.1 Draw with an appropriate sampling instrument a small portion of the material from different parts of each container selected (*see* Table 1). The total quantity of the material drawn from each container shall be sufficient to conduct the tests for all the characteristics given in **2** and shall be not less than 250 g.

B-3.1.2 Mix thoroughly all portions of the material drawn from the same container. Out of these portions, equal quantities shall be taken from each selected container and shall be well mixed up together so as to form a composite sample weighing not less than 0·5 kg. This composite sample shall be divided into three equal parts, one for the purchaser, another for the supplier and the third for the referee.

B-3.2 Referee Sample — The referee sample consisting of a composite sample marked for this purpose shall bear the seals of the purchaser and the supplier. It shall be kept at a placed agreed to between the purchaser and the supplier and shall be used in case of dispute between the two.

B-4. TESTS

B-4.1 Tests for all characteristics given in **2** shall be conducted on the composite sample.

B-5. CRITERIA FOR CONFORMITY

B-5.1 A lot shall be declared as conforming to this specification if the composite sample satisfies the requirements for each of the characteristics listed in **2**. If the requirements for any of the characteristics are not met, the lot shall be declared not to have satisfied the requirements of the specification.